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PETITION FOR EXTENSION OF TIME

Applicants hereby request a one-month extension of time extending the time for response from February 3, 2007 up to and including March 3, 2007. The Commissioner is hereby authorized to charge the required \$120.00 extension fee to Deposit Account No. 23-1703. Any other fees which may be due for any reason in connection with this Petition may likewise be charged.

MAR 02 2007

REMARKS

Upon entry of the amendments herein, claims 1, 2, 27-34 and 36-39 remain pending in the application. Claims 1, 2 and 32 have been amended herein; and claim 35 has been canceled. Claims 29, 31-34 and 36-39 currently stand withdrawn from consideration pending their being rejoined to the other pending claims upon determination of allowable subject matter.

In the first place, the Examiner has indicated that the scope of subject matter being considered has been expanded, stating that "the R4 substituent will be considered to the extent it also includes six-membered heterocyclic containing a single nitrogen heteroatom." It would appear that the Examiner meant to indicate that it is the scope of substituent R₁ that was expanded, and Applicants are proceeding on that assumption.

Claims 1, 2, 27, 28, 30 and 35 have been rejected under 35 U.S.C. §112, first paragraph as not being enabled for the recited scope of substituent R₁. With respect to this substituent, the Examiner asserts that "[T]here is no enablement for pKa 1-6.5, 13.3-15, no [sic] cycloalkyls no [sic] C₄ to C₆ alkyl or all other heterocyclic groups other than pyridyl."

In response, Applicants have amended claim 1 to further limit the scope of substituent R₁. The scope of the basic groups has been limited to amino, amidino and guanidino groups; as a consequence, claim 35 has been canceled. Furthermore,

cycloalkyl and aryl groups have been deleted from the definition of R_1 . These amendments have been made in the interest of expediting prosecution of the application to allowance and do not constitute acknowledgment by Applicants of the validity of the Examiner's assertion with respect to the enabled scope of R_1 . It should be noted, in fact, that cycloalkyls have been deleted from the definition of R_1 despite the inaccuracy of the Examiner's assessment. Instant Example 15 is a compound wherein R_1 is cycloalkyl.

While Applicants have acceded in these ways to the Examiner's limiting of the scope of R_1 , they have drawn the line at the Examiner's assertion that there is no enablement for " C_4 to C_6 alkyl or other heterocyclic groups other than pyridyl." This attempt to limit the scope of the claims is unacceptable, even in the interest of expediting prosecution.

It is noted in the first place that the Examiner acknowledges enablement for " CH_2-CH_2 alkyl" but then asserts the nonenablement of C_4-C_6 alkyl, thus leaving out C_3 alkyl altogether. In any event, there is no basis or precedent for the Examiner's assertion that the various examples of compounds wherein R_1 is C_2 alkyl do not enable compounds wherein R_1 is C_4-C_6 alkyl or for the implication that compounds containing alkyl groups of more than two carbons are patentably distinct from compounds containing C_2 -alkyl groups. It must be recognized that

"a generic concept inclusive of the elected species" (the Examiner's words in an earlier Office Action) would encompass compounds wherein R_1 is C_{2-6} alkyl.

In fact, if the claimed compounds were presently limited to ones in which R_1 is C_2 alkyl and if the Examiner were to find a prior art reference which disclosed compounds differing from the instant compounds in containing larger alkyl groups, for example, C_3 -alkyl groups, he would surely cite the reference as rendering obvious the present compounds wherein R_1 is C_2 alkyl. In other words, the Examiner would invoke homology considerations and assert that the disclosed prior art compounds containing alkyls of more than 2 carbons would be expected to have the same properties as the present compounds. Thus, there can be no basis for asserting that disclosure of compounds wherein R_1 is in the smaller end of the narrow range of alkyls does not enable compounds wherein R_1 is in the larger end of said range, or for implying that this range of alkyl groups within the present compounds represents multiple inventions.

Furthermore, there can be no basis for any contention by the Examiner that conducting a search for compounds wherein R_1 is C_2 - C_6 alkyl represents an undue burden compared to the search for compounds wherein R_1 is C_2 alkyl.

It is also noted that in the Examiner's discussion of Wands factors and other allegedly relevant case law and MPEP

guidelines, these citations are applied only in the context of "guidance as to what other rings might be suitable." In other words, the Examiner does not even attempt to apply his arguments to the consideration of the portion of the definition of substituent R_1 concerned with alkyl groups.

With respect to the particular issue of rings, there is no merit to the Examiner's assertion that there is no enablement for R_1 being a heterocyclic group other than a pyridyl group. In a June 3, 2005 telephone discussion with the undersigned, the Examiner indicated that "six-membered heterocyclyl containing a single heteroatom, which heteroatom is nitrogen," i.e., the present language of the claims, was acceptable. The amendments made to claims 1 and 2 in Applicants' June 29, 2005 Amendment and Response reflect the oral agreement between the Examiner and the undersigned.

While Applicants certainly recognize that the content of telephone discussions, if not made known in the form of a formal interview summary, are not part of the record per se, they do not understand the basis for the Examiner's attempt to further restrict the heterocyclyl moieties to pyridyl groups. Even the Examiner's expressed modification of the restriction requirement, set forth on page 2, lines 1-3 of the present Office Action, contradicts this further limitation of considered subject matter.

With or without the Examiner's prior telephonic acknowledgment as to an appropriate scope of heterocyclic rings with respect to R₁, it is irrefutable that the multiple examples of the instant application, which examples were discussed with the Examiner on June 3, 2005, comprise compounds wherein R₁ can be a pyridyl or piperidyl group, the latter also being "six-membered heterocyclyl containing a single heteroatom, which heteroatom is nitrogen." Thus, there is no basis whatsoever for the Examiner's current assessment of the limitations of enabling disclosure; there is sufficient enablement meeting the requirements of U.S. patent practice to warrant the present scope of the claims with respect to substituent R₁ when said substituent is a heterocyclyl moiety.

The Examiner has cited various cases in trying to justify the enablement rejection. However, these cases are inapt in light of the facts of the present case. For example, in *In re Fisher*, the Board held that the claims were insufficiently enabled because they did not positively identify the entire chemical structure of the claimed compounds. In the *Fisher* case, the claims recited polypeptides comprising "at least 24 amino acids..." No guidance whatsoever was provided as to the number and/or identity of the additional amino acids that were to be components of the claimed compounds beyond the 24 that were specified to be a part of those compounds. This is nothing

like the present situation wherein, particularly in the wake of Applicants' further limitation of the claims, all portions of the claimed compounds are positively identified.

In *In re Surrey*, the Board ruled that there were no examples of some of the types of compounds encompassed by the generic claim. However, again, this is not reflective of the facts of the present case. Particularly in view of the further limitation of the scope of the claims made by Applicants during the course of prosecution, it must be acknowledged that there is sufficient exemplification in the instant specification of the subclasses of compounds now recited in the pending claims.

Accordingly, the Examiner's attempt to limit the subject matter in the manner set forth in the present Action cannot be sustained. The enablement rejection must be withdrawn in light of the amendments that Applicants have made to the claims herein.

The claims currently under consideration have also been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. As the particular basis for this rejection, the Examiner cites the presence in the claims of the language "basic group" and "pKa from 1 to 15." In view of the amendments herein to the claims, these issues are moot, and the rejection must be withdrawn.

Claim 1 has been objected to, the Examiner asserting that "subscripts are missing from the 2 formulas on page 4, 8th line." It is Applicants' understanding that the Examiner is referring to a portion of the definition of substituent R₆ in claim 1, said portion reciting that R₆ is an "H₂N-C(Z)-CONH-C(Z)- or H₂N-C(Z)- group." It further appears that the Examiner believes that a subscript, presumably "2," should follow each of the three instances where "(Z)" occurs in the formulae. However, this belief is in error.

It is, and always was, Applicants' intention that, as currently recited in the definition of R₆, there be only one substituent Z in each instance; thus, no subscript is required. One of skill in the art would recognize that, in the absence of a subscript following (Z), the fourth valence position of carbon is filled with a hydrogen in each instance. It is standard with respect to carbons in line formulae of the type used in the definition of R₆ that only the non-hydrogen substituents on the carbons need be specified and that any nonspecified valence positions on the carbons are filled with hydrogens. This notwithstanding, claim 1 has been amended herein, in order to address the Examiner's concern, by the addition of H's to the formulae in question as appropriate. It must be emphasized that this amendment to the claim can in no way be construed as the addition of new matter.

Finally, claims 1, 2, 27, 28, 30 and 35 stand rejected under 35 U.S.C. §101 as constituting double patenting over certain claims of U.S. Patent Nos. 6,737,416 and 6,576,627, both to Fushihara et al. The Examiner has quoted the statute, even emphasizing a portion thereof. However, the meaning conveyed by the words of the statute, including the emphasized portion, make it clear that a double patenting rejection is inappropriate in the present case. As stated in MPEP §804, "[B]efore consideration can be given to the issue of double patenting, two or more patents or applications must have at least one common inventor and/or be either commonly assigned/owned or non-commonly assigned/owned but subject to a joint research agreement..." Neither of the patents cited by the Examiner meet any of these criteria; they do not share at least one inventor with the present application, they are not commonly assigned with the present application and the Assignees in question are not subject to a joint research agreement. Accordingly, this rejection must be withdrawn.

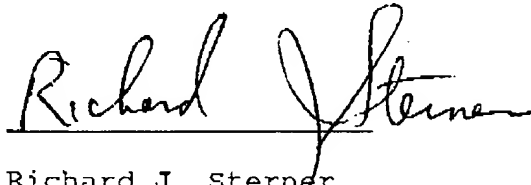
In view of the amendments and arguments set forth above, all outstanding issues have been properly addressed. Reconsideration and allowance of the application with claims 1, 2, 27, 28 and 30 are respectfully requested. It is further requested that the currently withdrawn claims, directed to formulations, methods of treatment and processes for

preparation, be rejoined and also allowed. Should any other matters require attention prior to allowance of the application, it is requested that the Examiner contact the undersigned.

No additional fees should be due in connection with this communication. However, should it be determined that an additional fee is required for any reason, the Commissioner is hereby authorized to charge it to Deposit Account No. 23-1703.

Dated: March 2, 2007

Respectfully submitted,

A handwritten signature in cursive script, reading "Richard J. Sterner", written over a horizontal line.

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